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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,871	08/15/2001	C. Alexander Turner JR.	LEX-0216-USA	1901

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LEXICON GENETICS INCORPORATED  
8800 TECHNOLOGY FOREST PLACE  
THE WOODLANDS, TX 77381-1160

EXAMINER

TURNER, SHARON L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/930,871

Applicant(s)

TURNER ET AL.

Examiner

Sharon L. Turner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 6-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____    |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> | 6) <input checked="" type="checkbox"/> Other: <u>copy of Genbank AC010127</u> |

### **DETAILED ACTION**

1. The amendment filed 3-31-03 has been entered into the record and has been fully considered. Claims 2 and 5 is canceled. Claims 1, 3-4, and 6-8 are pending.

### **Information Disclosure Statement**

2. It is noted that reference CK as cited on the PTO-1449 apparently references two separate citations. First a reference by Escayg et al., that has been provided and secondly a Genbank/EMBL sequence citation noted as AC010127. The PTO-1449 has been amended to reflect the publication date of the Escayg reference as April 2000 and the AC010127 accession as created 14 September 1999. A copy of the AC010127 accession was not provided by applicant but a copy is provided herein. The accession is not cited duplicatively on a PTO-892 as it is considered to have already been referenced on the PTO-1449.

### **Election/Restriction**

3. Applicant's election without traverse of Group VI, nucleic acids encoding SEQ ID NO:12 is noted. All pending claims are drawn to the elected invention.

### **Specification**

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The claims are no longer directed to peptides. No information regarding the elected subject matter of nucleic acids encoding SEQ ID NO:12 is provided.

**Claim Rejections - 35 USC § 101**

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1, 3-4 and 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification discloses isolated novel human proteins (NHPs) that share structural similarity with mammalian ion channel proteins, in particular sodium ion channel proteins and voltage-gated sodium ion channel proteins, see in particular specification pp. 1-2, paragraph spanning. Also disclosed are the related reagents and methods of use including to nucleic acids, peptides antibodies, vectors, host cells and methods of producing the recombinant peptide. While the specification generically discusses these types of peptides, the specification fails to note any particular data specific to SEQ ID NO:12 other than the particular SEQ ID NO and fails to establish the peptides use in any particular method of use, treatment, diagnostic or prognostic related to any specific function or disorder. While the artisan recognizes multiple types of sodium ion channels with divergent structure and function, the artisan fails to recognize a specific and substantial use of SEQ ID NO:12. Further, the specification fails to teach the particular function and/or significance of the SEQ ID NO:12 molecule. The molecule is not noted to be any particular type of sodium channel, i.e., voltage gated, sodium/potassium ion pump or otherwise, and the specification fails to teach how the

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purported sodium ion channel may be used or manipulated so as to provide for any particular use, function or effect in any particular tissue, disorder, prognostic, diagnostic, treatment or disease. Thus, the disclosed nucleic acids merely constitute research reagents for further experimentation to discover a "real-world" use for the nucleic acids. The recited uses also do not constitute a well-established utility because the structure and function of the molecule is not established in the prior art. As recognized by Skolnick et al., Trends in Biotech., 18(1):34-39, 2000, the skilled artisan is well aware that there is an unpredictable nature in the ability of encoding nucleic acids to predict structural and functional activities for any particular protein or protein family, and particularly in ion function. Even when highly homologous and conserved residues are known only experimental research can confirm the artisan's best guess, see in particular Skolnick, abstract and Box 2. Thus, the assignment of instant SEQ ID NO:12 as a purported sodium ion channel based upon homology is not sufficient based on the knowledge of the skilled artisan and the data presented in instant specification to provide either specific or substantial utility to the claimed sequences. The artisan would not know how to use the molecules to provide for significant or substantial benefit. The function and/or significance of the nucleic acids encoding the peptide molecule remains to be established. Thus, for these reasons there does not appear to be either a specific and substantial asserted utility or well-established utility for the claimed nucleic acid sequences.

### **Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3-4 and 6-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

#### **Status of Claims**

9. No claims are allowed.
10. The claimed invention is free of the prior art. WO0138564 of record as reference CH is the closest prior art of record.
11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.



Sharon L. Turner, Ph.D.  
July 14, 2003